

PRIME ASTHMA RELIEF- epinephrine capsule

PRIME ASTHMA RELIEF- epinephrine

DRNATURALHEALING

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIVE INGREDIENT

Epinephrine, USP 0.22 mg per capsule/dose

PURPOSE

Bronchodilator

USE

For temporary relief of mild symptoms of intermittent asthma:

- wheezing
- tightness of chest
- shortness of breath

WARNINGS

Asthma Alert:

Because asthma may be life threatening, see a doctor if you:

- are not better in 20 minutes
- get worse
- need more than 6 inhalations in 24 hours
- use more than 4 inhalations in 24 hours for 3 or more days a week
- have more than 2 asthma attacks in a week

These may be signs that your asthma is getting worse

Do not use

- unless a doctor said you have asthma
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs taken for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have:

- ever been hospitalized for asthma
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- seizures
- narrow angle glaucoma
- a psychiatric or emotional condition
- trouble urinating due to an enlarged prostate gland

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Ask a doctor or pharmacist before use if you are

- taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions
- taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain)

When using this product

- **your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.**
- Your risk of heart attack or stroke increases if you:
 - have a history of high blood pressure or heart disease
 - **take this product more frequently or take more than the recommended dose**
- avoid foods or beverages that contain caffeine
- avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect

Stop use and ask doctor if

- your asthma is getting worse (see Asthma alert)
- you have difficulty sleeping
- you have a rapid heartbeat
- you have tremors, nervousness, or seizure

PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- **do not use more than directed**
- adults and children 4 years of age and over: 1 capsule is for one inhalation at one time
- inhalation not more often than every 3 hours
- do not use more than 12 inhalations in 24 hours
- the use of this product by children should be supervised by an adult
- children under 4 years of age: ask a doctor

1) The active ingredient in a dry powder is 0.22 mg per capsule (the concentration is 1% epinephrine in the total weight of the dry powder)

2) For use in a dry powder inhaler for holding the No. 3 capsule.

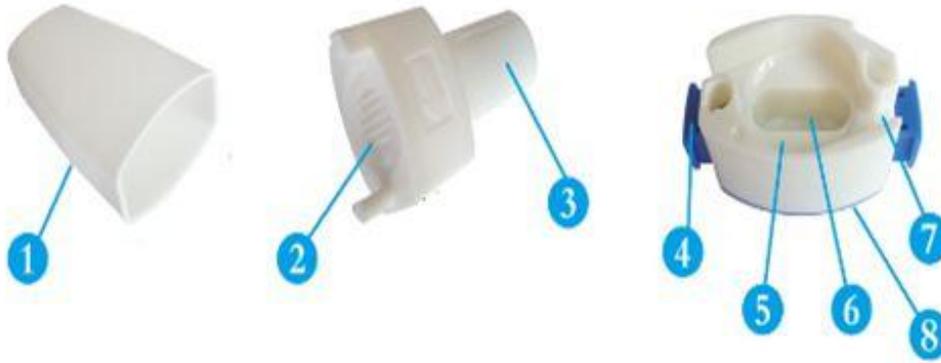
3) Should orally inhale at least two times after the capsule is pierced to make sure all dry powder is inhaled into the lung

4) Instructions for Inhalation:

INHALER PARTS

CE Certificate No.: ESC/10021212v

ISO13485:2003 Certificate No.: 11711Q0M0004R0S



1. Protection cap

2. Grate

3. Mouthpiece

4. Push button

5. Rotation chamber

6. Capsule cavity

7. Air supply

8. Back piece

A. Inhaler parts:

B. Instructions for using the dry powder inhaler:

Wash and dry your hands completely before touching the inhaler and capsule.



(1) Remove the cap.



(2) Hold the inhaler at base and turn the mouthpiece in direction of the arrow.



(3) Obtain 1 capsule from the blister package just prior to use.



(4) Open inhaler by turning mouthpiece as indicated. Load 1 capsule in the capsule-chamber of the inhaler. Do not put the capsule directly into the top of the mouthpiece. Twist the mouthpiece to the closed position.



(5) Hold the inhaler upright, push/click two blue buttons inwards all the way. Let go of the blue buttons. Do not press the blue buttons more than 1 time. The chances of the capsule breaking into pieces will be increased if the capsule is accidentally pierced more than once.

(6) With the inhaler away from your mouth, prepare by breathing out (exhaling) all the way. Do not blow or exhale into the mouthpiece.



(7) Hold the inhaler horizontally. Place your mouth over the mouthpiece and close your lips tightly around it. Inhale quickly and deeply.

(8) Hold your breath for count of ten, or as long as is comfortable. Breathe out gently. You will need to inhale at least twice from one capsule in order to get the full dose.

(9) After the dose, open the mouthpiece, remove the used capsule, and take a look at the used capsule. It should be pierced and empty. If so, dispose of it properly. If the capsule does not look pierced, put the capsule back into the device capsule-chamber, repeat steps 7, 8 and 9.

(10) Cover the mouthpiece and dust cap for storage.

(11) After your Inhalation, throw away the empty capsule properly as it is bio-degradable. Do not store the capsule in the inhaler. Put the mouthpiece back to your inhaler device and twist the mouthpiece in a clockwise direction until it is tight. Do not over-tighten.

HOW SUPPLIED

1. Epinephrine Inhalation is a dry powder, USP 0.22 mg, in one number 3 capsule.
2. NDC 15343-104-20, each dose is in an individual capsule. Twenty capsules are packed in one blister. The dry powder in the capsule is in a ready-to-inhale form.

STORAGE AND HANDLING

1. Protect from light
2. Place in a dry area
3. Avoid excessive heat
4. Store between 2°C and 24°C (36°F and 75°F)

INACTIVE INGREDIENT

Lactose

REGULATORY STATUS

OTC Monograph 2013, 21 CFR Part 341.16 and 341.76 Bronchodilator

COMMENTS AND QUESTIONS

1-888-658-8108

Monday through Friday, 8:00 a.m. to 5:00 p.m. (Eastern Standard Time)

Manufactured for: DrNaturalHealing, Inc. 111 McCoy Street Milford, DE 19963, USA
Info@DrNaturalHealing.com

Principal Display Panel

DRUG FACTS	
Active Ingredient (in each Inhalation) Epinephrine 0.22 mg	Purpose: Bronchodilator
USES: For temporary relief of mild symptoms of Intermittent bronchial asthma: wheezing, tightness of chest, shortness of breath.	
WARNINGS: Asthma alert: Because asthma can be life threatening, please see a doctor if you: • are not better in 20 minutes, or get worse. • need more than 6 inhalations in 24 hours. • use >4 inhalations in 1 day for 3 or more days a week. • have more than 2 asthma attacks in a week. These may be signs that your asthma is getting worse.	
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DIRECTIONS: Adults & children 4 years of age and older: 1 dose/capsule Children's use of this drug should be supervised by an adult. 1. Place 1 capsule in the dry powder inhaler 2. Use 2 fingers to press the 2 buttons to puncture capsule 3. Take one deep oral inhalation. See detail in User Guide.	
INACTIVE INGREDIENTS: Lactose	
Manufactured for: DrNaturalHealing 111 McCoy Street Milford, DE 19963	
	



Prime Asthma Relief KIT

Temporarily Relieves Mild Symptoms of Intermittent Bronchial Asthma

- Shortness of Breath
- Wheezing
- Tightness of Chest



Same Active Ingredient as in Primatene® Mist



1 Inhaler & 20 Capsules

Patent Pending

Drop



Click



Breathe



DRUG FACTS

Active Ingredient (in each inhalation) Epinephrine 0.22 mg	Purpose: Bronchodilator
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USES:
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Asthma alert: Because asthma can be life threatening, please see a doctor if you:

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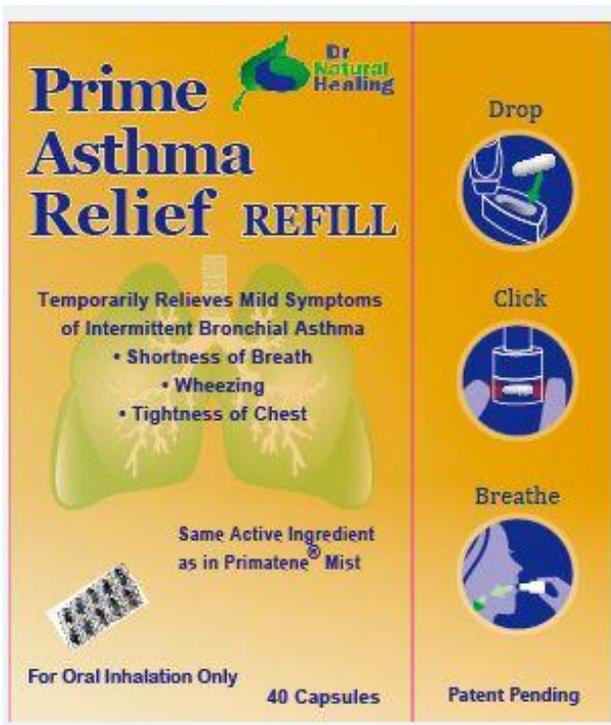
DIRECTIONS:
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Children's use of this drug should be supervised by an adult.
 1. Place 1 capsule in the dry powder inhaler
 2. Use 2 fingers to press 2 buttons to puncture capsule
 3. Take one deep oral inhalation
 Please see detail in User Guide

INACTIVE INGREDIENTS:
Lactose

Manufactured for:
DrNatural-Healing Inc.
111 McCoy Street
Milford, DE 19963, USA



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Prime Asthma Relief REFILL

Dr Natural Healing

Temporarily Relieves Mild Symptoms of Intermittent Bronchial Asthma

- Shortness of Breath
- Wheezing
- Tightness of Chest

Same Active Ingredient as in Primatene[®] Mist

For Oral Inhalation Only 40 Capsules

Drop

Click

Breathe

Patent Pending

PRIME ASTHMA RELIEF			
epinephrine capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15343-105
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.22 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	49.78 mg

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	3mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15343-105-40	1 in 1 CARTON		
1		40 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/21/2014	

PRIME ASTHMA RELIEF

epinephrine kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15343-104
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15343-104-20	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	20

Part 1 of 1

PRIME ASTHMA RELIEF

epinephrine capsule

Product Information

Route of Administration RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.22 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	3mm
Flavor		Imprint Code	
Contains			

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OTC monograph final	part341		

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OTC monograph final	part341	08/21/2014	

Labeler - DRNATURALHEALING (129613308)

Registrant - DRNATURALHEALING (129613308)

Establishment

Name	Address	ID/FEI	Business Operations
Star Health and Beauty LLC		013506838	manufacture(15343-104)

Revised: 6/2014

DRNATURALHEALING